RESEARCH CURRICULUM

ETHICAL ISSUES IN CLINICAL RESEARCH

February 22, 2017 – April 12, 2017

This course will consist of 8 sessions beginning on Wednesday, February 22nd and ending on April 12th. We meet at 5pm in room MSB 2.103. The course will address both accepted and controversial aspects of the ethics of clinical research. It is intended to be both conceptually interesting and practically useful, particularly for young investigators.

Prior to the first class each participant is requested to read and comment (a one paragraph precis will do) on the following paper and submit it to the office.

Emanuel, E, Wendler, D, Grady, C: “What Makes Clinical Research Ethical” JAMA 2000, 283: 2701-2711

To receive credit for the class attendance will ordinarily be required for no fewer than 7 of the 8 sessions. (Persons in extraordinary circumstances may be granted prior approval to view the video of the missed class. See course director)

The course is designed as a lecture course. However, there will be an honors section which will require additional reading and additional discussion time. You must sign up separately in order to participate in the honors section. If you do so, you will have additional papers to read or questions to consider. But, participation in small discussion groups immediately following the lecture is mandatory in order to earn the honors designation.

The lecture is designed to end at 5:45. Those enrolled in the honors section will stay for the small group discussion which will end at 6:30. Reading list will be provided for each lecture.

Lecture 1) Unproved Therapies: Can We Better Serve our Patients?
Feb. 22
Jon E Tyson, MD, MPH & Susan H Wootton, MD

Ethical Dilemmas in Medical Innovation & Research: Distinguishing Experimentation from Practice


Lecture 2) Tuskegee and Its Aftermath
March 1
Simon Whitney, MD
Reading to be provided

Lecture 3) Financial Conflicts of Interest in Academic Medicine: Why This
March 8  
**Matters More Now Than Ever**  
Leonard Zwelling, MD

Read introductory chapter

**Lecture 4**  
March 15  
**Informed Consent- An Exploration**  
Rebecca Lunstroth, J.D., M.A.

Readings to be provided

**Lecture 5**  
March 22  
**Conceptions and Misconceptions in Contemporary Research Ethics**  
John Lantos, MD

SUPPORT and the Ethics of Study Implementation: Lessons for Comparative Effectiveness Research from the Trial of Oxygen Therapy for Premature Babies  

Learning the Right Lessons from the SUPPORT Controversy  
Lantos JD, Arch Dis Child Fetal Neonatal Ed Jan 2014 vol 99, pp14-15

**Lecture 6**  
March 29  
**The Learning Health Care System and its Impact on Comparative Effectiveness Research**  
Charles C. Miller, PhD

Informed Consent, Comparative Effectiveness and Learning Health Care  

**Lecture 7**  
April 5  
**Flawed Clinical Research & its Aftermath: The Wakefield Case and Impact on Immunization Policy**  
Susan H Wootton, MD

Lancet Retracts 12 year old Article Linking Autism to MMR Vaccines  
CMAJ: MARCH 9, 2010 pp 182(4)

The Age Old Struggle Against the Antivaccinationists.  

**Lecture 8**  
April 12  
**Mock IRB**

cases to be provided

Discussants:  
Kathleen Kennedy, MD, MPH  
Rebecca Lunstroth, JD  
Charles C. Miller, PhD